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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,521	12/14/2001	(Bruce) Yiqun Wang	1001.1465101	9132

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	**PAPER NUMBER**
1772	5

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,521	WANG ET AL.	
	Examiner	Art Unit	
	Christopher P Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 01 May 2002 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to a catheter shaft, classified in class 428, subclass 36.9.

II. Claims 19-21, drawn to a method of making a catheter, classified in class 264, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another process such as injection molding the admixed polymeric material in a mold having a pre-formed curve.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with David Crompton on January 16, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

5. The drawings are objected to because Fig. 2 on page 1 of the drawings should be labeled Fig. 3, to be consistent with the specification. A proposed drawing correction or corrected

drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "21" and "28" have both been used to designate the crystals, also reference number 21 is not described in the specification, so it is suggested that reference number 21 in Figure 2A be changed to reference number 28. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:

Page 7, line 9 should read a single manifold "port" 18 not portion.

On page 12, lines 20 and 21, the reference number following "curved regions" should be 22 not 32.

On page 13, line 3, the reference number following "regions" should be 22 not 20.

On page 17, line 22, the reference number following "member" should be 44 not 42.

On page 17, line 23, the reference number following "assembly" should be 10 not 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6-12, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ju et al (USPN 5,599,325).

Ju et al anticipate a catheter shaft comprising a polymeric tubular member having a lumen extending the length therein, wherein the tubular member includes a pre-formed bend along a portion of the length of the tubular member (see abstract and Figure 1). The polymeric material making up the shaft comprises polyamide and polyether block amide (col.4, l.25-27, col.5, l.7-10, and col.5, l.60-63). The polymeric material forming at least a portion of the pre-formed bend includes a sufficient

quantity of titanium dioxide. The titanium dioxide is added in amount between 0.001 and 0.5 wt% in the pre-formed bend portion (col.6, l.1-5). Titanium dioxide is a nucleating agent, and even though Ju et al is using the titanium dioxide as a pigment, it is still a nucleating agent. Furthermore, the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. See MPEP 2112. The catheter shaft is a portion of a guide catheter or vascular catheter (col.1, l.8-20). The shaft is also used as a portion of a biliary catheter. Note the intended use of the shaft in different types of catheter that require the same properties of flexibility and stiffness receive little patentable weight. The linear shaft segment (reference number 12, Figure 1) has a different rigidity than the pre-formed bend segment (reference number 16, Figure 1), because the linear shaft segment is a two-layered composite and the pre-formed bend section is a one-layered material made from PEBA and polyamide (col.5, l.60-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4-5 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ju et al (USPN 5,599,325) in view of Muni et al (USPN 5,316,706) and in further view of Jansen (Nucleating agents for Partly Crystalline Polymers).

Ju et al teach all that is claimed in claims 1 and 10, but fail to explicitly teach adding any other nucleating agents besides titanium dioxide to at least the pre-formed bend segment of the catheter shaft. However, Muni et al teach a catheter having at least two segments having different rigidities and other properties (see abstract). Muni et al further teach that catheters used in the vascular system are required to have a

number of apparently conflicting physical characteristics. For example, the catheter must be sufficiently rigid in the proximal region to enable its distal end to be maneuvered by manipulation of its proximal end (col.1, l.15-20). At the same time it is necessary for the catheter's distal end to be sufficiently soft so as not to traumatize the vascular walls when being advanced and sufficiently flexible to enable it to readily follow a potentially tortuous vascular path (col.1, l.23-27). Muni et al teach that to create different rigidities in different segments of the catheter shaft with out the use of a multi-piece structure (col.1, l.45-55), as taught by Ju et al, selected portions or segments of the shaft are created with different crystalline structure. This variation in crystallinity imparts substantially varied physical properties to different portions of the same catheter, most notably providing for a substantial range in stiffness (col.2, l.43-50). Furthermore, although increased polymerization results in a stiffer structure, more highly crystallized material can be curved into a tighter radius without kinking (col.2, l.61-64). Muni et al further teaches that the crystallinity of the catheter may be varied in any of a plurality of zones throughout its length (col.4, l.20-22). One of ordinary skill in the art would have recognized that the crystallinity of the polymeric material forming the catheter

shaft is varied in order to provide stiffer and more flexible segments of the catheter in order to balance the need for the catheter to be flexible so that it does not traumatize the vascular walls and yet sufficiently rigid in the proximal end to enable its distal end to be maneuvered by manipulation of the proximal end, as taught by Muni et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to vary the crystallinity of different segments of the pre-formed bended catheter shaft of Ju et al in order to form a catheter that balances the requirements for flexibility and rigidity without the disadvantages of a multi-piece structure, as taught by Muni et al.

Muni et al fail to explicitly teach using a nucleating agent in the polymeric material forming the catheter shaft, in order to crystallize segments of the shaft. However, Jansen teaches that nucleating agents produce high degrees of crystallinity resulting in increased hardness, elasticity modulus, tensile strength, and yield point compared with the unnucleated material. Jansen also teaches that by adding nucleating agents to a polymer the crystallization process is initiated with less supercooling and is completed after shorter cooling times (p.867). Jansen also teaches that when adding

nucleating agents the concentrations used are up to 0.5%, because higher than that do not, as a rule, produce any further enhancements of the nucleation effect (p.865). The nucleating agent is chosen based on the polymer used to form the article, such as polyethylene terephthalate or polyamide. Nucleating agents for polyethylene terephthalate are chosen from the group consisting of talc, kaolin, titanium oxide, salts of monocarboxylic or polycarboxylic acids, montan wax and montanic ester salts, polyethylene, polypropylene, and copolymers of ethylene and unsaturated carboxylic esters (p.868-869). Nucleating agents for polyamides are chosen form the group consisting of silica, molybdenum disulfide, iron sulfide, titanium oxide, talc, and sodium phenylphosphinate (p.870). One of ordinary skill in the art would have recognized that for economical reasons nucleating agents are added to polymeric material that will be crystallized because the crystallization process using nucleating agents is initiated with less supercooling and is completed after shorter cooling times, as taught by Jansen.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to add a nucleating agent to the catheter formed by the teachings of Ju et al and Muni et al combined, in order to make

the crystallized segments more economically, as taught by Jansen.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yoshifumi et al (USPN 4,931,538); Mills et al (USPN 5,340,884); Sun (USPN 6,358,450); Fanselow et al (USPN 5,562,127); Peterson et al (USPN 5,836,926); Toray Ind Inc (JP 62-288652 A); Gluck et al (USPN 6,254,949); Wang et al (USPN 6,465,067); Pathak et al (USPN 6,176,871); Matsumoto (USPN 5,516,565); Lurie et al (USPN 6,001,085); Beals (USPN 6,524,296).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
February 6, 2004

/David Pyon/
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

2/6/04